highest for PILs (p<0.001). Interaction analyses revealed that for one-page formats; the information load reduces, information anxiety reduces and product knowledge increases to a greater extent in high involvement scenario. **CONCLUSIONS:** The PILs had significantly higher patient comprehension as compared to the current practice and text-only prototypes. Increasing involvement further improves product knowledge, intention to read and attitude towards leaflet. The FDA could consider these findings and provide guidelines to design a concise prescription drug information leaflet to eventually improve the expected outcomes associated with these information sources.

PHP77

A COMPARATIVE STUDY ON PATIENT SAFETY CULTURE FOR PHARMACISTS IN JAPAN

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OBJECTIVES: This study aims to evaluate safety culture dimensions among pharmacists using Hospital Survey on Patient Safety Culture (HSOPSC) developed by AHRQ. **METHODS:** We surveyed nationwide the situation of patient safety culture in 37 hospitals (18,960 persons) between 2011 and 2012FY, which were allowed for additional costs on patient safety countermeasures under the social insurance medical fee schedule in Japan. **RESULTS:** We classified 37 hospitals into three groups by number of beds; A group's bed number was 20 to 200 (six hospitals), B group's was 201 to 400 (twelve hospitals), and C group's was more than 401 (19 hospitals). The overall response rate was 87.9% (16,670/18,960 persons). Number of respondents in A group was 996 (1,116 persons; response rate: 89.2%) including 19 pharmacists, number of respondents in B group was 3,319 (3,674 persons; response rate: 90.3%) including 100 pharmacists, and number of respondents in C group was 12,355 (14,170 persons; response rate: 87.2%) including 340 pharmacists. The overall average positive response rate (RR) for the 12 patient safety dimensions of the HSOPSC was 46.6% in A group, 52.7% in B group and 51.0% in C group. In terms of occupational categories, RRs for pharmacists were 48.3% in A, 56.8% in B and 50.0% in C, RRs for physicians were 44.3% in A, 52.9% in B and 50.7% in C, and RRs for nurses were 43.4% in A, 52.8% in B and 51.6% in C, in each. RR for pharmacists was the highest among these three professionals in A and B groups. In terms of pharmacists, RRs in B group was the highest among three groups. **CONCLUSIONS:** The HSOPSC measurement provides the evidence for assessment of patient safety culture for pharmacists in Japan's hospitals. This result suggested that pharmacists might be highly concerned with patient safety in Japan.

PHP78

FACTORS THAT IMPACT REPORTING OF ADVERSE DRUG EVENTS BY PHARMACISTS: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Spontaneous reporting of adverse drug events (ADEs) by pharmacists helps ensure safe medication use; an important aspect of pharmaceutical care. This systematic review summarizes published survey articles regarding determinants of ADE reporting by pharmacists **METHODS:** A literature search was conducted to identify original survey articles regarding pharmacists' knowledge, attitudes and demographic factors associated with frequency of ADE reporting. Search engines used included PubMed, CINHAL and Web of Science.For each survey article, the following data were extracted: pharmacists working setting, sample size, survey delivery, response rate, reporting rate, demographic factors, knowledge and attitudes associated with reporting **RESULTS:** Only 32 of the 820 articles identified met the study requirements. The number of respondents in the studies included in this review ranged from 20 to 643. Response rate ranged from 26.4% to 100%. Self – administered questionnaires were used in 47% (15/32) and 41% (13/32) surveyed both hospital and community pharmacists. A study of Canadian pharmacists found that 65% had reported an ADE, followed by 59% and 32% of pharmacists in the UK and the US respectively. Pharmacists were found to have favorable attitude toward reporting (7 studies).Years of work experience as pharmacist was associated with significantly increased ADE reporting in 2 studies. Pharmacists in hospital settings reported significantly more ADEs than pharmacists in community/retail settings (4 studies).Lack of knowledge of pharmacovigilance concepts, systems and/or the ADE reporting process were significant barriers to reporting among 72%; uncertainty that a specific drug is responsible for a particular ADE in 38%; and lack of time in 34% of studies. The factor most frequently recommended to improve reporting was special training/education programs related to pharmacovigilance concepts and ADE reporting (16/32). **CONCLUSIONS:** To improve reporting of ADE by pharmacist, educational interventions to address gaps in knowledge and attitudes could be implemented within pharmacy curriculum or as part of continuing education.

PHP79

PATIENTS' EXPECTATIONS AND INTENTIONS TO RECEIVE MEDICATION COUNSELING FROM COMMUNITY PHARMACISTS

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OBJECTIVES: While pharmacist provided counseling has proven effective in positive patient drug outcomes, only between 40-67% of patients are receiving this service. As the pharmacy profession moves towards providing greater patient care services, patients' intentions to receive pharmacist provided counseling are not well understood. The objectives were to elicit modal salient behavioral beliefs, normative referents and control beliefs of patients regarding receiving community pharmacist' provided counseling and determine the factors that influence intention to receive counseling (i.e. legal requirements and awareness of MTM services). **METHODS:** Focus groups were conducted with a convenience sample of community-pharmacy patients in Houston, TX, using a semi-structured interview guide with 14 open-ended questions. The theory of planned behavior was used as the theoretical framework to guide the focus group discussions. Each session was audio-recorded, transcribed, and participant responses were analyzed for qualitative content. **RESULTS:** Two, 60 minute focus groups (Total N=12) were conducted. Time constraints and privacy issues presented as major themes in the discussions. Regarding advantages/disadvantages, participants emphasized the importance of counseling for the discussion of potential drug interactions and side effects of their medications and felt that their doctor would approve of them speaking with a pharmacist about their medications. However, both patient and pharmacist' time constraints presented as a barrier to counseling. The majority of participants also stated that they would receive counseling more readily if it were provided in a more private environment. Only one participant was aware of MTM services and medication counseling requirements by law, however the majority stated that if they were aware of this mandate they would more readily accept pharmacist provided counseling. **CONCLUSIONS:** The identification of barriers to pharmacist provided counseling, specifically privacy and time limitations, may be beneficial for creating specific interventions that would increase patients' intentions to receive pharmacist provided counseling.

PHP80

THE STATE OF THE COMPARATIVE EFFECTIVENESS RESEARCH (CER) ENVIRONMENT: SURVEYS OF STAKEHOLDERS AND INFLUENTIALS

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OBJECTIVES: Describe the state of CER, its use and impact on medical decision-making, and perceptions about the future for CER, application of evidence, and impact of CER **METHODS:** Internet and mail survey of health care stakeholders, including government, health plans, researchers, human resources specialists, employers, and trade organizations, that are influential in or affected by CER; telephone follow-up to maximize response. **RESULTS:** The 2014 survey, the fourth in a series begun in 2010, found that health care stakeholders recognize the importance of CER but continue to believe, as in previous surveys, that significant impact of CER on treatment decisions is still in the future. PCORI is now recognized by most stakeholders as a leading organization in establishing research priorities, funding and monitoring research, and translating and disseminating the research. The 2014 survey indicates a clear need for more and better evidence. Only five percent of respondents believe the evidence base is sufficient to inform treatment decisions, and just 10 percent indicate that real-world evidence is being used to support decision-making. About 15 percent of stakeholders indicated that variability in individual patient treatment response in being widely considered in treatment decisions. **CONCLUSIONS:** The 2014 survey indicates continued belief among stakeholders that CER is important to them, but the most significant impacts are yet to be felt. The environment for CER is changing, and PCORI is recognized as a key organization in the spectrum of activities related to CER. The evidence base is not sufficiently complete to inform treatment decisions, and the influence of real-world evidence and variability in patient response are not yet apparent and warrant monitoring.

PHP81

SHORTAGES OF DRUGS WITH APPROVED ORPHAN INDICATIONS IN THE UNITED STATES

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OBJECTIVES: We assessed the prevalence of shortages of drugs approved for orphan indications and evaluated the characteristics of the orphan drugs reported in short supply in the US. **METHODS:** Orphan approval data were collected from the US FDA webpage. Shortage data were provided by the Drug Information Service, University of Utah Hospitals and Clinics (UU). The prevalence of shortages was estimated as a percentage of the total number of orphan indications approved in the US as of September 25, 2013. **RESULTS:** The FDA approved 449 orphan indications for 338 products (66.0% molecular entities, 23.7% therapeutic biologics, and 10.4% other biologics). Injectable products represented 59.7%, oral products 30.7% and other 9.6% of the orphan indications. The average number of orphan indications per year increased from 6.9 in 1983-1989 to 23.3 in 2010-2013. The UU listed 1,740 shortages in the period 2000-09/25/2013. A total of 146 (8.4%) of shortages were for products with orphan indications. Shortages were estimated to affect 28.5% of FDA approved orphan indications (128 shortages out of 449 orphan indications approved by the FDA), this included 36.0% of indications for molecular entities, 15.8% of for therapeutic biologics, and 6.7% for biologics. The average estimated duration of shortages was 252.1±322.1 days for drugs with orphan indications and 270.3±336.3 days for other drugs (differences not statistically significant). The reason for the shortage was unknown for 50.2% of the shortages. Drugs with orphan indications were significantly more likely to have manufacturing problems as the reason for the shortage (67.6%) than other drugs (52.9%, p=0.02). **CONCLUSIONS:** Over one-fourth of the drugs with approved orphan indications were reported in short supply in the US. Problems with manufacturing represented most of the reported causes of shortages. Additional research is needed to assess the risk factors, causes and clinical impact of orphan drug shortages.

PHP82

GLOBAL SNAPSHOT OF THE ECONOMIC BURDEN OF DISEASE-RELATED MALNUTRITION IN HOSPITALIZED PATIENTS

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